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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/753,750 11/29/96 LO

R 63637-0102

EXAMINER

HM12/1016

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MINNIFIELD, N

ART UNIT

PAPER NUMBER

1645

24

DATE MAILED:

10/16/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/753,750

Applicant(s)

LO ET AL

Examiner
N. M. Minnifield

Group Art Unit
1645



☒ Responsive to communication(s) filed on Aug 1, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 30-51 is/are pending in the application

Of the above, claim(s) 42 and 48 is/are withdrawn from consideration

☒ Claim(s) 30-41 and 43-47 is/are allowed.

☒ Claim(s) 49-51 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

CONTINUED EXAMINATION UNDER 37 CFR 1.114 AFTER FINAL REJECTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 3, 2000 has been entered.
2. Applicants' amendment filed July 3, 2000 is acknowledged and has been entered. Claims 30, 43, 44, 46 and 47 have been entered. Claims 30-41, 43-47 and 49-51 are now pending in the present application. All rejections have been withdrawn in view of applicants' amendment to the claims and/or comments. It is noted that the following is a new grounds of rejection being set forth.
3. Claims 49-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims are directed to vaccines comprising polynucleotide fragments as well as methods of treatment administering

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DNA and methods of treatment of a mammal infected with *P. haemolytica* by administering DNA. Applicants set forth written description in the specification of the vaccine and the methods however, there is no guidance in the specification that any of these methods (claims 49-50) and the vaccine product (51) will yield the desired results of treatment of infection or protection from *P. haemolytica*. Further, what is the purpose for the treatment as set forth in claim 49. With regard to DNA vaccines and methods of treatment of infection by administering DNA or nucleic acid molecules to a mammal, there are difficulties involved in these methods. Although some data might suggest that nucleic acid vaccines are more similar to live attenuated vaccines such as polio or measles, the precise mechanisms are not well understood; how does the nucleic acid constructs enter cells at the site of administration (Smith, Vaccine, 1994). The pivotal safety concern associated with the use of these compositions is whether the vaccine will integrate into the genome of the vaccinated subjects. The question of genetic toxicity has not been addressed. Integrated vaccines may result in insertional mutagenesis through the activation of oncogenes or inactivation of tumor suppressor genes. An integrated nucleic vaccine may result in chromosomal breaks or rearrangements, thus this becomes a need to assess the potential of the nucleic acid vaccine to recombine with endogenous host DNA sequences (Smith). In view of the above, the specification has not set forth sufficient guidelines with regard to how to

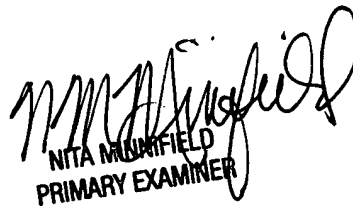
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make and use the claimed invention of a method of treatment of infection or protection of a mammal using a nucleic acid vaccine.

4. All claims appear to be free of the prior art.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


NITA MINNIFIELD
PRIMARY EXAMINER

N. M. Minnifield

October 10, 2000